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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
| 08/182,183 | 05/23/94 | LIN | L SYNE225/CA-U 3-225E |
| | | 18N2/1211 | EXAMINER |
| | | SWANSON & BRATESCHUN, L.L.C. | ALLER, M |
| | | 8400 EAST PRENTICE AVENUE | |
| | | SUITE 200 | ART UNIT |
| | | ENGLEWOOD, CO 80111 | PAPER NUMBER |
| | | 1817 | |

DATE MAILED: 12/11/97 - Confirmed w/CXR.
Allen on 12/19/97 88k

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Corrected date in 12/19/97 88k

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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|------------------------------|--------------------------------------|-----------------------------------|
| Office Action Summary | Application No. 08/182,183 | Applicant(s) Lin et al. |
| | Examiner Marianne Allen | Group Art Unit 1817 |

Responsive to communication(s) filed on Sep 16, 1997

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 88-94 and 117-158 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) 88-94, 118-120, 135, 150, and 152-157 is/are allowed.

Claim(s) 117, 121-134, 136-149, 151, and 158 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1817.

Applicant's arguments filed 16 November 1997 have been fully considered but they are not

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persuasive.

Applicant is reminded of the requirement to point to page and line number for supporting basis for all new claim limitations.

Claims 26, 28-29, 31, 34, 42-55, 75-86, and 95-116 have been cancelled. Claims 117-158

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have been newly added. Claims 88-94 have been previously indicated as allowable.

The disclosure is objected to because of the following informalities:

Claim 135 lacks a terminal period (".").

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Applicant's new claims have demonstrated that the instant application is not in compliance with one or more of the requirements of 37 CFR § 1.821 through 1.825.

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The pre-pro GDNF amino acid sequences in the Figures are not present in the Sequence Listing. SEQ ID NO: 25 is a nucleic acid sequence not an amino acid sequence. (See for example claim 124.) Applicant is reminded that they are required to list separately the amino acid sequences if they are discussed as a separate sequence. (See MPEP 2423.02.) Here the nucleic acid and amino acid sequences are disclosed and discussed separately.

It is noted that any corrections to the sequence listing will require submission of a new CRF.

A new sequence listing will need to be submitted to replace the present one in the specification. A

statement that the content of the paper and computer readable copies are the same and contain no new matter would also need to be submitted.

Appropriate correction is required.

5 Claims 117, 121-134, 136-149, 151, and 158 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

10 Claims 122 and 151 recite "further comprising a codon encoding an amino-terminal methionine residue." No basis has been pointed to for this limitation and none is apparent in the specification. Applicant is requested to point to page and line number supporting these embodiments.

15 Claim 124 recites "further comprising nucleotides encoding a pre-pro amino acid sequence." The specification does not appear to indicate that amino acid residues 1-77 may be present on both rat and human mature GDNF sequences. It does not appear that the pre-pro sequences are the same for each of these species. Applicant is requested to point to page and line number supporting these embodiments.

Claim 136 recites "at least 90% identical." However, the specification at page 13 discloses in excess of (that is, greater than) 90%. No basis has been established for 90% itself.

20 Claims 117, 121, and 125 recite "under conditions of reduced stringency." As set forth in the prior Office action with respect to claim 26, the specification does not provide basis for this limitation. The recitation of "wherein said conditions include" does not obviate this deficiency. The claims are not limited to these specifically recited conditions and the specification does not set forth

a general concept of the metes and bounds of "reduced stringency." One practicing the invention would not be able to determine when the limitations of the claims had been met. Nor does the specification appear to contemplate sequences that hybridize to those that are 70% identical to named sequences. Applicant is requested to point to page and line number supporting this general concept.

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Claims 117, 121, and 124-125 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 117, 121, and 125 recite "wherein said conditions include." It is unclear if these recited conditions are merely examples of suitable conditions (and not specifically required by the claim) or whether these conditions must be used although other conditions could be used in addition.

Claims 124 and 125 refer to an amino acid subsequence of SEQ ID NO: 25. However, SEQ ID NO: 25 is not an amino acid sequence. It is a nucleic acid sequence.

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It is believed that all pertinent arguments have been addressed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for response to this final action is set to expire **THREE MONTHS** from the date of this action. In the event a first response is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the

THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

5 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen, whose telephone number is (703) 308-0666. The examiner can normally be reached on Monday-Friday from 6:30 am to 3:00 pm.

10 If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, Ph.D., can be reached on (703) 308-4310. Official FAX communications may be directed to either (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Marianne P. Allen
MARIANNE P. ALLEN
PRIMARY EXAMINER
GROUP 1800